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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/662,129	09/12/2003	Daniel J. Cooke	279.445US1	9076

21186 7590 01/27/2006

SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH
1600 TCF TOWER
121 SOUTH EIGHT STREET
MINNEAPOLIS, MN 55402

EXAMINER	
KRAMER, NICOLE R	

ART UNIT	PAPER NUMBER
3762	

DATE MAILED: 01/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/662,129	COOKE ET AL.	
	Examiner	Art Unit	
	Nicole R. Kramer	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 September 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12 September 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1, 2, 4, and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 3,683,993 ("Mansfield").

Mansfield discloses an electro-medical system comprising a container including an electrical device therein (metal case 3 forms a sealed conductive enclosure about a pulse generating circuit; see col. 2, lines 12-34) and a porous first covering over the container (pacer support 1 is a fabric body made from relatively open machine knitted, polyester mesh; see col. 1, lines 34-56 and col. 2, line 63 - col. 3, line 38), wherein the porous first covering includes a porous communication to the container (since the fabric body receives and holds the metal case 3 while permitting the exterior of the package to serve as a return electrode for the pulse generating circuit as disclosed at col. 1, lines

38-42, Examiner considers the fabric to include a "porous communication to the container").

With respect to claim 2, Mansfield discloses that the support may be formed of a porous polyester (polyester fiber mesh; see col. 2, lines 67-68).

With respect to claim 4, Examiner considers the container (metal case 3) to be completely covered in the porous covering (see for example, col. 4, lines 22-23, which discloses that the porous fabric substantially totally encloses the housing).

With respect to claim 12, the container houses a cardiac pacemaker.

3. Claims 1, 4, 10, and 12-14 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,433,730 ("Alt").

Alt discloses an electro-medical system comprising a container including an electrical device therein (metallic can 38) and a porous first covering over the container (pouch 55 comprises a woven net or mesh; see col. 12, lines 6-23), wherein the porous first covering includes a porous communication to the container (since the pouch enhances the electrical properties of the metallic can, Examiner considers the fabric to include a "porous communication to the container").

With respect to claim 4, Examiner considers the container (metallic can 38) to be completely covered in the porous covering (see, for example Fig. 6).

With respect to claim 10, Alt discloses that the system may include a plurality of leads (transvenous lead 36 as discussed at col. 11, lines 42-55 and extension lead 60 as discussed at col. 12, lines 27-61).

With respect to claim 12, the container houses a cardiac pacemaker (see col. 11, lines 24-41).

With respect to claims 13-14, the container houses a monitor for sensing cardiac electrical activity, which necessarily includes monitoring heart rate, and/or other physiologic parameters (see col. 11, lines 24-41).

4. Claims 1-2, 4, 16-17, and 19-21 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,755,762 ("Bush").

Bush discloses an electro-medical system comprising a container (non-electrode portions of the lead are electrically insulated with an insulator 34, 35, 36, 37, which may be silicone rubber, polyurethane, or nonporous fluoropolymer tubing located between the conductor and beneath the porous covering 10; see col. 5, lines 43-67. Examiner considers this tubing to be "a container.") including an electrical device therein (Examiner considers the conductor to be "an electrical device;" see Fig. 2) and a porous first covering over the container (continuous porous covering 10), wherein the porous first covering includes a porous communication to the container (the pore size is chosen to be small enough to discourage tissue ingrowth but large enough that current can be delivered through the covering when the pores are filled with body fluid; see col. 3, lines 10-16).

With respect to claims 2 and 17, Bush discloses that the porous tubular covering may be made of various materials, including fluoropolymer, polyester, polyurethane, and PTFE (see col. 6, lines 1-13).

With respect to claim 4, Examiner considers the container to be completely covered in the porous covering (see, for example Fig. 2).

With respect to claim 16, Bush discloses a lead including a lead proximal end, a lead body, and a distal end including an electrode (electrodes 16 and 20), wherein lead includes a porous covering (continuous porous covering 10) that includes a porous communication to the lead, and wherein the porous covering includes a pore structure that repels in vivo fibrotic tissue ingrowth (the pore size is chosen to be small enough to discourage tissue ingrowth but large enough that current can be delivered through the covering when the pores are filled with body fluid; see col. 3, lines 10-16).

With respect to claims 19-20, Bush discloses a dielectric coating over at least one of the proximal end and the lead body (non-electrode portions of the lead are electrically insulated with an insulator 34, 35, 36, 37, which may be silicone rubber, polyurethane, or nonporous fluoropolymer tubing located between the conductors and beneath the porous covering 10; see col. 5, lines 43-67).

With respect to claim 21, Bush discloses that lead 12 may be one of a plurality of leads (see col. 2, line 66 - col. 3, line 2).

5. Claims 1-3, 5-11, and 16-21 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,704,604 ("Soukop et al.").

Soukop et al. discloses a system and method for selectively promoting tissue ingrowth on, or adjacent to, an implantable medical device utilizing a layer or porous PTFE tubing or tape, with the pores having a pore size to either selectively prevent

substantially all tissue in-growth and/or selectively promote tissue in-growth at predetermined locations (see Abstract). Soukop et al. discloses that the disclosed invention may be utilized on the enclosure/can of an implantable medical device (see col. 8, lines 1-10), which necessarily includes an electrical device housed therein. Because the layer(s) are porous, body fluids that are retained within the pores allow these layers to conduct electricity when the lead is implanted (see col. 5, lines 45-50).

With respect to claims 2 and 17, Soukop et al. discloses that the porous covering is constructed from porous PTFE.

With respect to claims 3, 5-7, 11, 16, Soukop et al. discloses a lead (i.e., leads 600 and 604 of Fig. 6) having a distal end including an electrode/coil (electrodes 602 and 604). Soukop et al. discloses several embodiments, including embodiments in which the electrode/coil is covered with a porous second covering (see, for example, col. 7, lines 8-65) and embodiments in which portions of the lead body itself is covered with a porous second coating (see, for example, col. 5, line 7 - col. 6, line 59). In each embodiment, one of the porous layers has a pore size to prevent substantially all tissue in-growth (i.e., layer 308 of Figs. 3 and 4 and the inner layer disposed around the defibrillation electrodes).

With respect to claims 8-9 and 19-20, Soukop et al. discloses that the lead may include a dielectric coating over the proximal end (see col. 6, lines 9-43). The dielectric coating may be formed of silicone or other biomedical materials.

With respect to claims 10 and 21, Soukop et al. discloses that the system further includes a plurality of leads (i.e., leads 600 and 604 of Fig. 6).

With respect to claim 18, Soukop et al. discloses that the disclosed invention may be utilized on the enclosure/can of an implantable medical device (see col. 8, lines 1-10).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 3, 5-11, and 13-14, 16-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 3,683,993 ("Mansfield") in view of U.S. Patent No. 5,755,762 ("Bush").

As discussed above, Mansfield discloses an electro-medical system comprising a pacer housing (metal case 3 forms a sealed conductive enclosure about a pulse generating circuit; see col. 2, lines 12-34) having a porous first covering over the housing (pacer support 1 is a fabric body made from relatively open machine knitted, polyester mesh; see col. 1, lines 34-56 and col. 2, line 63 - col. 3, line 38). The disclosed system further includes a lead coupled to the container (lead 17), the lead including a distal end electrode (21). Mansfield fails to disclose that the electrode is covered with a porous second covering. Bush discloses a lead including a distal end electrode (electrode 16) that includes a porous second covering for discouraging tissue in-growth (continuous porous covering 10 covers both lead body 14 and electrode 16;

see col. 3, lines 3-23). It would have been obvious to one having ordinary skill in the art at the time of applicant's invention to substitute the lead (17) of Mansfield for the lead disclosed in Bush in which the lead body and the distal end electrode are covered with a porous second covering in order to utilize a lead which prevents tissue in-growth on or around the lead body and the distal electrode.

With respect to claim 5, Bush discloses that electrode 16 may be of any defibrillation or pacing electrode construction as known in the art, including coils (see col. 3, lines 16-23).

With respect to claims 8-9 and 19-20, Bush discloses a dielectric coating over at least one of the proximal end and the lead body (non-electrode portions of the lead are electrically insulated with an insulator 34, 35, 36, 37, which may be silicone rubber, polyurethane, or nonporous fluoropolymer tubing located between the conductors and beneath the porous covering 10; see col. 5, lines 43-67).

With respect to claims 10 and 21, Bush discloses that lead 12 may be one of a plurality of leads (see col. 2, line 66 - col. 3, line 2).

With respect to claims 11 and 17, Bush discloses that the porous tubular covering may be made of various materials, including fluoropolymer, polyester, polyurethane, and PTFE (see col. 6, lines 1-13).

With respect to claims 13-14, Mansfield discloses that the container (metal case 3) houses a cardiac pacemaker (see col. 11, lines 24-41). Mansfield fails to specifically disclose that the pacemaker may also function as a monitor, such as a monitor for monitoring heart rate or blood pressure. Examiner takes Official Notice that it is well

known in the art for pacemakers to include monitoring functionality, including means for monitoring blood pressure, temperature, oxygen, heart rate, respiration, etc... It would have been obvious to one having ordinary skill in the art at the time of applicant's invention to modify the pacemaker of Mansfield to include monitoring functionality as is well known in the art in order to provide more physiological pacing therapy, or in order to record such monitoring health data for later review by a physician.

8. Claims 15 and 22-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 3,683,993 ("Mansfield") in view of U.S. Patent No. 5,562,715 ("Czura et al.").

As discussed above, Mansfield discloses an electro-medical system comprising a pacer housing (metal case 3 forms a sealed conductive enclosure about a pulse generating circuit; see col. 2, lines 12-34) having a porous first covering over the housing (pacer support 1 is a fabric body made from relatively open machine knitted, polyester mesh; see col. 1, lines 34-56 and col. 2, line 63 - col. 3, line 38). Mansfield discloses that the fabric body receives and holds the metal case 3 while permitting the exterior of the package to serve as a return electrode for the pulse generating circuit (see col. 1, lines 38-42). Mansfield fails to disclose a dielectric coating over the metallic can, and a passageway through the dielectric coating to form an exposed portion of the container. Czura et al. teaches that both unipolar and bipolar stimulation are known in the art, and one may be preferable to the other in many cases (see col. 1, lines 9-67). Czura et al. teaches a pacemaker (10), the housing of which is constructed of a

conductive material (see col. 3, line 65- col. 4, line 3) coated with a dielectric material such as silicone rubber or paralene (see col. 4, lines 4-11). Detachable tabs (28) are provided on each side of the pacemaker in order to allow a physician to selectively expose a portion of the casing to serve as an indifferent electrode when it is desirable for the device to pace in a unipolar mode (see, for example, col. 3, lines 3-11). It would have been obvious to one having ordinary skill in the art at the time of applicant's invention to modify the pacemaker system of Mansfield such that the metallic can has a dielectric coating and detachable tabs for selectively exposing a portion of the can to serve as an indifferent electrode as taught by Czura et al. in order to enable the pacemaker system to operate in either a unipolar or bipolar mode, depending upon which stimulation mode is preferable.

With respect to claim 23, Mansfield discloses that the support may be formed of a porous polyester (polyester fiber mesh; see col. 2, lines 67-68).

9. Claims 24-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 3,683,993 ("Mansfield") in view of U.S. Patent No. U.S. Patent No. 5,562,715 ("Czura et al."), as applied to claim 22 above, and further in view of U.S. Patent No. 5,755,762 ("Bush").

As discussed above, Mansfield discloses an electro-medical system comprising a pacer housing (metal case 3 forms a sealed conductive enclosure about a pulse generating circuit; see col. 2, lines 12-34) having a porous first covering over the housing (pacer support 1 is a fabric body made from relatively open machine knitted,

polyester mesh; see col. 1, lines 34-56 and col. 2, line 63 - col. 3, line 38). The disclosed system further includes a lead coupled to the container (lead 17), the lead including a distal end electrode (21). Mansfield fails to disclose that the electrode is covered with a porous second covering. Bush discloses a lead including a distal end electrode (electrode 16) that includes a porous second covering for discouraging tissue in-growth (continuous porous covering 10 covers both lead body 14 and electrode 16; see col. 3, lines 3-23). It would have been obvious to one having ordinary skill in the art at the time of applicant's invention to substitute the lead (17) of Mansfield for the lead disclosed in Bush in which the lead body and the distal end electrode are covered with a porous second covering in order to utilize a lead which prevents tissue in-growth on or around the lead body and the distal electrode.

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

U.S. Patent No. 5,090,422 (Dahl et al.) teaches a porous coating or enclosure for a defibrillation electrode that substantially prevents tissue in-growth.

U.S. Patent No. 5,466,252 (Soukop et al.) teaches an implantable lead having a conductor (12) with a surrounding layer of dielectric material (14) and an additional coaxial, exterior later of porous PTFE (16).

U.S. Patent No. 5,609,622 (Soukop et al.) teaches an implantable electrode having a coiled conductor with a surrounding layer of electrically conductive polymeric material and an additional coaxial, exterior later of porous PTFE.

U.S. Patent No. 5,931,862 (Carson) teaches a continuous sheath of porous PTFE for the outside of a lead body and the electrodes, wherein the pore size is chosen to discourage tissue ingrowth. Carson further teaches a wetting agent (30) applied to the porous plastic.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nicole R. Kramer whose telephone number is 571-272-8792. The examiner can normally be reached on Monday through Friday, 8 a.m. to 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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George Manuel
Primary Examiner